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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,581	04/30/2002	Mortimer M. Civan	22253-67116 US	1751

27730 7590 08/01/2003

DILWORTH PAXSON LLP
3200 MELLON BANK CENTER
1735 MARKET STREET
PHILADELPHIA, PA 19103

EXAMINER
JAGOE, DONNA A

ART UNIT	PAPER NUMBER
1614	8

DATE MAILED: 08/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,581	CIVAN ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 38-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 38-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Claims 1 and 38-93 are presented for examination.

Information Disclosure Statement

The information disclosure statement filed 20 June 2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered with the exception of the US patents listed as A through E which have been reviewed and considered. See enclosed copy of PTO FORM 1449.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 38-43, 47-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Drug Facts and Comparisons (1994).

The claims are drawn to a method of regulating, controlling or modulating aqueous humor secretion comprising administering a modulator of one or more antiports. The antiports are Na^+/H^+ exchanger (the NHE-1 antiport) and a Cl^-/HCO_3^-

exchanger (the AE2 antiport). Examples of the modulators are timolol, amiloride and amiloride analogs and cariporide.

Drug Facts and Comparisons teach timolol, a beta blocker, to be employed to reduce elevated and normal intraocular pressure with or without glaucoma (page 2287). The mechanism appears to be a reduction of aqueous production, and a slight increase in outflow facility. Regarding claims to modulation of the antiports, this action is considered to be inherent. Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in Ex *parte Novitski*, supra, the claims are directed to preventing a malady or disease with old and well-known compounds or compositions. It is now well-settled law that administering compounds inherently possessing a protective utility anticipates claims directed to such protective use. Arguments that such protective use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975).". In the instant application, Applicants' failure to distance the proffered claims

from the anticipated prophylactic utility, renders such claims anticipated by the prior inherent use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 38-41, 44-45, 49-50, 52-53, 55-63, 65-66, 68-76, 78-79, 8187, 89-90 and 92-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burke, U.S. Patent No. 5,215,991.

The claims are drawn to a method of regulating, controlling or modulating aqueous humor secretion comprising administering a modulator of one or more antiports. The antiports are Na^+/H^+ exchanger (the NHE-1 antiport) and a Cl^-/HCO_3^- exchanger (the AE2 antiport). Examples of the modulators are timolol, amiloride and amiloride analogs and cariporide.

Burke teaches methods and pharmaceutical compositions of Na^+/H^+ exchange inhibitors which are employed to lower intraocular pressure (IOP) and for treatment of intraocular hypertension (increased intraocular pressure)(see abstract). Na^+/H^+ exchange inhibitors such as amiloride analogs improve the ocular hypotensive profile of various alpha 2 agonists when co-administered with the alpha 2 agonist (column 1, line 56 to column 2, line 5). It differs in that it does not teach glaucoma. It teaches intraocular hypertension. Since both intraocular hypertension and glaucoma both result in increased intraocular pressure, it would have been obvious to administer amiloride to lower the intraocular pressure associated with glaucoma. Motivation to employ amiloride for glaucoma would come from the teachings of Burke that amiloride successfully treats intraocular pressure associated with intraocular hypertension.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burke as applied to claims 1 and 38-41, 44-45, 49-50, 52-53, 55-63, 65-66, 68-76, 78-79, 8187, 89-90 and 92-93 above, and further in view of Scholz et al. U.S. Patent No. 6,348,476.

The claim is drawn to a method of regulating, controlling or modulating aqueous humor secretion comprising administering a modulator of one or more antiports. The antiports are Na^+/H^+ exchanger (the NHE-1 antiport) and a Cl^-/HCO_3^- exchanger (the AE2 antiport) wherein cariporide is the modulator.

Burke teaches methods and pharmaceutical compositions of Na^+/H^+ exchange inhibitors which are employed to lower intraocular pressure (IOP) and for treatment of intraocular hypertension (increased intraocular pressure)(see abstract). Na^+/H^+ exchange inhibitors such as amiloride analogs improve the ocular hypotensive profile of various alpha 2 agonists when co-administered with the alpha 2 agonist (column 1, line 56 to column 2, line 5).

It does not teach cariporide.

Scholz et al. teach that cariporide is a NHE inhibitor. It does not teach cariporide to lower intraocular pressure. Since Burke teaches Na^+/H^+ exchange inhibitors (NHE inhibitors) to lower intraocular pressure (IOP) it would have been obvious to employ cariporide to lower intraocular pressure associated. It would have been made obvious to one of ordinary skill in art at the time it was made to employ cariporide to lower intraocular pressure since Burke teaches inhibitors of NHE to lower intraocular pressure and Scholtz teaches that cariporide is an inhibitor of NHE. Such a modification would

have been motivated by the reasoned expectation of producing a composition, which is effective in comprehensively treating persons suffering from glaucoma.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (703) 306-5826. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Donna Jagoe
Patent Examiner
Art Unit 1614

dj
July 27, 2003

PHYLLIS SPIVACK
PRIMARY EXAMINER